



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/790,417

03/01/2004

Charles A. Mesko

MESK / 30

1471

26875 7590 05/29/2008
WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/790,417	Applicant(s) MESKO, CHARLES A.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/4/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,7-19,22,24,27,28,30,33 and 36-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,7-19,22,24,27,28,30,33 and 36-60 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed **1/5/08** presents remarks and arguments to the office action mailed **10/5/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 4-5, 7-19, 22, 24, 27-28, 30, 33, 36-60 are pending, claims 4, 30, and 33 have been amended.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 depends on a cancelled claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-5, 7, 13, 24, 27-28, 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to a pharmaceutical composition for administration to a mammal, comprising first ingredient *Eurycoma longifolia* jack and a second ingredient effective to stimulate the production of cGMP. The, the scope of the claims includes numerous second ingredient effective to stimulate the production of cGMP recitation of a very broad genus such that the common attributes or characteristics concisely identifying members of the genus are exemplified, and, because the claimed genus is so highly variable, the recitation is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed as not every cGMP would be capable of the providing the function as claimed with the first ingredient. Thus, Applicant was not in possession of the claimed genus.

Claims 4 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

Art Unit: 1614

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim recites a third ingredient for stimulating an increase in blood flow. The, the scope of the claims includes numerous third ingredients effective to stimulate an increase in blood flow, the recitation of a very broad genus such that the common attributes or characteristics concisely identifying members of the genus are exemplified, and, because the claimed genus is so highly variable, the recitation is insufficient. Thus, Applicant was not in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a limitation of a cancelled claim. Claim 7 depends on claim 6 and claim 6 is cancelled.

Double Patenting

A Terminal Disclaimer is filed, the rejection is therefore withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5, 7-11, 12-19, 22, 24, 27-28, 30, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al., US 5,595,970 taken with Ang et al. Arch Pharm Res. 2001, 24(5):437-40, 2001 (ABSTRACT ONLY (new)) and Chwalisz et al., US 5,906,987 and Coral-Cure www.coral-cure.com/mens-health in view of Chen et al. Exp. Opin. Ther. Patents and Bulk Nutrition 1, 2002, 3 pages and Chiou et al. Planta Med. 2001 67:282-284 (new).

Garfield et al., teach a pharmaceutical composition comprising a hormone (progesterin) and a nitric oxide as required in part by instant claims 4, see col. 4, lines 50-54. Nitric oxide activates guanylate cyclase to increase the cellular content of cGMP. See col.1, line 67 bridging col. 2, lines 1-3. With regard to the second ingredient inhibiting the activity of atleast one enzyme is obvious as nitric oxide inhibits nitric oxide synthase activity absent factual evidence as required by instant claim 13. The reference fails to teach the Eurycoma longifolia jack.

Ang et al. teach Eurycoma longifolia jack has gained notoriety as a symbol of man's ego when administered. One of ordinary skill in the art would be motivated to administer a natural herb that has been found to function the same way as the hormone testosterone.

Chwalisz et al., teach a pharmaceutical composition comprising a hormone (testosterone ester/testosterone) and a nitric oxide as required by instant claim 4 in part see col. 4, lines 20-32. Nitric oxide is an effector on cGMP. See col.2, lines 23-25.

Coral-cure teaches a homeopathic form 10X topical formulation comprising testosterone (hormone), chrysin, estrogen blocker, Tribulus L. Terrestris. Coral-cure also teaches the formulation including plurality of inactive ingredients such as saw palmetto extract for the use of overall prostate health, see pg 4, 3rd para from bottom as required by instant claim 30. Although, Coral-cure did not teach the plurality of active ingredients as those listed in instant claim 28, it does teach the cream comprises of various active homeopathic agents such as Mucana Pruriens, which is a dopamine stimulator, Ginkgo Biloba which increases blood flow. Based on the teaching and the target treatment one of ordinary skill in the art would be motivated to add other active natural ingredients that would act synergistically in producing the end targeted result. For example, this Coral-cure is for producing sexual stimulation, thus within the purview of one of ordinary skill in the art to add such ingredients. Nothing unobvious is seen in substituting one homeopathic agent for another as required by instant claims 27-28.

Chiou et al. teach the vasorelaxing effect of coumarins from *Cnidium monnieri*. It is taught that *Cnidium monnieri* comprises of asthole as required by instant claims 8- 10 and 33, stimulates nitric oxide production, increases the blood flow. See underlining.

Bulk Nutrition teaches a composition comprising L-arginine, *Cnidium* extract. It is known in the art to one of ordinary skill that l-arginine increases natural production of

Art Unit: 1614

nitric oxide and Cnidium Monnier increases nitric oxide release and inhibits PDE-5, when one uses the specification as a dictionary. The composition also includes a stimulant for blood flow such as xanthoparmelia Scabrosa. It is noted however, that the composition did not recite the ingredient as Epimedium sagittatum as the stimulant for increase blood flow, however, substituting one ingredient that function the same is within the purview of the one of ordinary skill in the art. Nothing unobvious is seeing in doing so. Therefore claims 11 and 13-18, 33, 36` are obvious. Also it is known that coumarins are from Cnidium Monnier, thus administering Cnidium Monnier is administering coumarin is regarded as administering osthole, therefore claims 8-11 are obvious as taught by Chiou et al. See underlining.

With regards to the phosphatidyl choline the vesicle carrier Chen and al. teach the use of phosphatidyl choline in topical application as in current claims 24 and 33 as a means of elevating plasma concentration of dehydroepiandrosterone to treat erectile function, see page 1039, last para, left col.

One of ordinary skill in the art would have combined the references recited above and included a phosphatidyl choline as the visicle carrier in claim 24 because the particles are liposomes and have means for binding to microorganisms present on the skin, for example those responsible for skin disorders and elevate blood plasma.

Therefore one of ordinary skill in the art would have been motivated to include a phosphotidyl choline because it is a major component of cellular membranes and functions in the transport of lipoproteins in tissues.

One of ordinary skill in the art would have used the homeopathic cream by coral-cure because it contains a testosterone in a cream, thus a vesicle operable for transporting the testosterone from the external body site to an internal second body site and stimulate blood flow to the organs needed. Also Eurycoma longifolia jack is known to have a testosterone enhancing property, thus substituting testosterone with Eurycoma longifolia jack would have been obvious since Eurycoma longifolia jack showed increase in levator ani muscle strength when administered to male rats. As to it being in the homeopathic form is obvious as these are natural agents used in diluted forms as understood by the Examiner, therefore instant claim 22 would be obvious to one of ordinary skill in the art in herbal medicine absent factual evidence. In the instant application the cream is rubbed on the penis wherein the steroid/hormone-testosterone stimulates are known to regulate nitric oxide synthesis and nitric oxide effector system cGMP. One of ordinary skill in the art would have been motivated to include in the pharmaceutical composition a Tribulus L. Terrestris because in some cultures, the tribulus terrestris plant has been used as a "tonic" to increase energy levels and treat sexual dysfunction (usually in males) as evident by <http://www.ironmagazine>.

As to the varying concentration recited in instant claims 5, 7, 12 and 19 the determination of a dosage having the optimum therapeutic index is well within the level of the ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get the maximum effect of the drug, hence the reference makes obvious the instant invention.

Thus, the claimed invention was prima facie obvious to make and use at the time it was made.

Claims 37-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al., US 5,595,970 taken with Ang et al. Arch Pharm Res. 2001, 24(5):437-40, 2001 (ABSTRACT ONLY (new)) and Chwalisz et al., US 5,906,987 and Coral-Cure www.coral-cure.com/mens-health in view of Chen et al. Exp. Opin. Ther. Patents and Bulk Nutrition 1, 2002, 3 pages and Chiou et al. Planta Med. 2001 67:282-284 (new) further in view of Mesko US 6,340,474 and McCoy et al. Proc. West. Pharmacol. Soc. 45:76-78, 2002.

The references are applied here as above in their entirety (limitations not addressed above is addressed below).

With regards to instant claims 46-50, it is the Examiners understanding that Mucuna Pruriens, which is a dopamine stimulator a source of L-dopa would comprise a hydroxylated amino acid.

However, Mesko teaches a composition comprising a first herbal extract, having an element which synthesizes a catecholamine see abstract. Further, the reference teaches the extract is a hydroxylated amino acid and synthesizes dopamine and is gotten from Mucuna Pruriens. See col. 4, lines 55-67 as required by instant claim 46-51. The reference further teaches Tribulus L. Terrestris has additional function when combined with Mucuna Pruriens as it results in increase of prosexual characteristics. See col. 5, lines 23-67 as required by instant claim, 52-55.

Art Unit: 1614

One of ordinary skill in the art would have been motivated to combine the references as the ingredients of the claimed invention is known in the art and the characteristic of the agents would be inseparable. MPEP 2112.01 states "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

McCoy et al teach Morinda Citrifolia is used to treat sexual dysfunction.

As to the second ingredient Morinda Citrifolia, McCoy et al teach Morinda Citrifolia is used to treat sexual dysfunction. It is known in the art that Morinda Citrifolia is used to treat sexual dysfunction, thus it is within the purview of one of ordinary skill in the art to add another agent that will enhance the overall activity of the composition when administered for the same treatment. Therefore, one of ordinary skill in the art would have been motivated to add an ingredient known to treat sexual dysfunction to a homeopathic formulation for the treatment of a sexual dysfunction. Thus one of ordinary skill in the art would have been motivated to combine the prior art and formulate a pharmaceutical composition with all the ingredients cited in the claimed invention because the ingredients have been used either separately or in combination for treating the same.

No claim is allowed.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
5/9/08

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

Application/Control Number: 10/790,417
Art Unit: 1614

Page 12